



Translation

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

. (PCT Article 36 and Rule 70)

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Applicant's or agent's file reference FLAMEL 0077	FUR FURITER ACTION Destiminary Byamination Report (Folill FC1/4 PAGE)						
International application No.	International filing date (day/		Priority date (day/month/year) 09 avril 2002 (09.04.2002)				
PCT/FR2003/001096	07 avril 2003 (07.04	1.2003)	09 aviii 2002 (09.04.2002)				
International Patent Classification (IPC) or national classification and IPC A61K 9/50							
Applicant FLAMEL TECHNOLOGIES							
This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.							
2. This REPORT consists of a total of	of 5 sheets, includ	ing this cover	sheet.				
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
These annexes consist of a total of sheets.							
3. This report contains indications re	clating to the following items:						
I Basis of the repor	I Basis of the report						
II Priority							
III Non-establishmer	nt of opinion with regard to nove	lty, inventive	step and industrial applicability				
IV Lack of unity of i							
V Reasoned stateme	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement						
VI Certain document	VI Certain documents cited						
VII Certain defects in	Certain defects in the international application						
VIII Certain observations on the international application							
Date of submission of the demand	Date	e of completion	n of this report				
27 octobre 2003 (27.		21 July 2004 (21.07.2004)					
Name and mailing address of the IPEA/EP		Authorized officer					
Facsimile No.		Telephone No.					



International application No.

PCT/FR2003/001096

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

I. Basis	of the report						
1. With	regard to the elements of the international application:*						
\boxtimes	the international application as originally filed						
$\overline{\boxtimes}$	the description:						
	pages 1-22	, as originally filed					
	pages	, filed with the demand					
	pages, filed	with the letter of					
\boxtimes	the claims:						
	1-20	, as originally filed					
	pages	as amended (together with any statement under Article 19					
	nages	, med with the Delimit					
	pages, filed	with the letter of					
\boxtimes	the drawings:						
	pages 1/2-2/2	, as originally filed					
	pages	, filed with the demand					
	pages , filed	i with the letter of					
	the sequence listing part of the description:	as originally filed					
i	pages	, as originally filed , filed with the demand					
	pages, file	d with the letter of					
the The	h regard to the language, all the elements marked above were available international application was filed, unless otherwise indicated under the selements were available or furnished to this Authority in the following the language of a translation furnished for the purposes of international application (under the language of publication of the international application (under the language of the translation furnished for the purposes of internations or 55.3). The regard to any nucleotide and/or amino acid sequence disclaiminary examination was carried out on the basis of the sequence list contained in the international application in written form. If it is together with the international application in computer readal furnished subsequently to this Authority in written form. The statement that the subsequently furnished written seque international application as filed has been furnished. The statement that the information recorded in computer readal been furnished.	which is: ional search (under Rule 23.1(b)). Rule 48.3(b)). ernational preliminary examination (under Rule 55.2 and/ losed in the international application, the international ing: ble form. m. ence listing does not go beyond the disclosure in the					
in	The amendments have resulted in the cancellation of: the description, pages the claims, Nos. the drawings, sheets/fig This report has been established as if (some of) the amendments beyond the disclosure as filed, as indicated in the Supplemental Belacement sheets which have been furnished to the receiving Office in this report as "originally filed" and are not annexed to this red 70.17). The amendments have resulted in the cancellation of: the description, pages the claims, Nos. This report has been established as if (some of) the amendments Belacement and the Supplemental Belacement sheets which have been furnished to the receiving Office in this report as "originally filed" and are not annexed to this red 70.17). The property of the description, pages The description of:	in response to an invitation under Article 14 are referred to port since they do not contain amendments (Rule 70.16					



v .	Reasoned statement under Article 35 citations and explanations supporting	5(2) with regard to novelt g such statement	y, inventive step or industrial appli	cability;
1.	Statement			
	Novelty (N)	Claims	1-20	YES
	,	Claims		NO
	Inventive step (IS)	Claims		YES
	mional o stop (-c)	Claims	1-20	NO
	Industrial applicability (IA)	Claims	1-20	YES
		Claims		NO NO

2. Citations and explanations

Reference is made to the following documents:

D1: EP-A-624 371

D2: WO 96 11 675 A

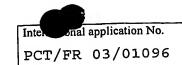
Except where otherwise indicated, reference is made to the passages of D1 cited in the search report. D2 is cited by the examiner. A copy is attached to the present written opinion.

Novelty

D1 describes acetylsalicylic acid microcapsules with a coating layer. Said microcapsules can be administered in the form of a suspension (example 4). The fact that the active ingredient is released by diffusion in the suspension medium is not mentioned. D2 describes coated microcapsules as defined in claim 1 (D2, page 9, line 4 to page 10, line 12), and the use thereof for preparing controlled-release systems having a plurality of classes of active ingredients (page 4, line 27 to page 15, line 10). Therefore, the subject matter of claims 1-20 appears to be novel over D1 and D2 (PCT Article 33(1) and (2)).

Even if a specific active ingredient could be selected,

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the subject matter of said claims are not considered to be inventive. D1 is the closest prior art. The present application differs therefrom by virtue of the fact that the microcapsules are formulated as a suspension. From the example given in D2, or the general therapeutic principle that a suspension is advantageous as compared, for example, with capsules or tablets in the case of patients who find it difficult to swallow (paediatric or geriatric patients), a person skilled in the art would arrive at the solution provided in the present application. The solvent phase would be saturated by the diffusion of the active ingredient from the microcapsules.

The prior art documents cited do not mention adding the free active ingredient to the suspension medium (claim 8). Nevertheless, this would be envisaged by a person skilled in the art seeking to provide for the immediate availability of at least a portion of the active ingredient.

For these reasons, the subject matter of claims 1-20 is not considered to be inventive (a13).

The active ingredient release profiles (claims 11 and 12) and the diffusion percentage of the active ingredients in the microcapsules (claim 5) are not mentioned in the prior art, but they appear to be a result that is sought rather than a precise definition of the invention. Therefore, said claims do not meet the requirements of PCT Article 6.